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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,911	10/11/2000	C. Alexander Turner JR.	LEX-0068-USA	9082

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	17

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/689,911	Applicant(s) TURNER ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 28 February 2003 (Paper No. 16) has been entered in full. Claim 2 is amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to the declaration as set forth at pg 3 of the previous Office Action (Paper No. 13, 24 September 2002) is *withdrawn* in view of the newly submitted declaration (Paper No. 15, 28 February 2003).

2. The rejection of claim 2 under 35 U.S.C. § 112, second paragraph, as set forth at pg 10-11 of the previous Office Action (Paper No. 13, 24 September 2002) is *withdrawn* in view of the amended claim (Paper No. 16, 28 February 2003).

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

3. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for the claims at pg 3-9 of the previous Office Action (Paper No. 13, 24 September 2002) and at pg 3-6 of the Office Action of 01 April 2002 (Paper No. 11).

Specifically, claims 1-8 are directed to an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2 and an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence from amino acid number 33 to amino acid number 141 of SEQ ID NO: 2. The claims also recite recombinant expression vectors and a host cell comprising the expression vector.

Applicant's arguments (Paper No. 16, 28 February 2003), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Applicant asserts that the specification identifies the presently claimed galanin family sequences as involved in a number of functions, including a role in inflammation (pg 1, lines 32-36). Applicant argues that this phenotype has been confirmed in genetically engineered mice that lack the murine homolog of the presently claimed sequence. Applicant contends that mice were created in which a portion of the murine homolog of the presently claimed galanin family sequence was deleted and then subjected to an intraperitoneal inflammation assay to assess the immune system challenge with zymosan. Applicant indicates that the homozygous animals showed an increase in total white blood cells compared to wild-type control, consistent with, as set forth in the instant application, the states role of this protein in inflammation.

Applicant's arguments have been fully considered but are not found to be persuasive. Although Applicant asserts that the claimed polynucleotide is involved in a number of different functions, such as inflammation (as evidenced by knockout mice), this assertion is credible, but not specific or substantial. The specification does not specifically disclose the generation of

knockout mice lacking the murine homolog of the claimed polynucleotide. The specification also does not disclose subjecting the knockout animals to intraperitoneal inflammation assays to assess the immune system challenge with zymosan. The specification only teaches that "transgenic animals that express a NHP transgene, or "knockouts" (which can be conditional) that do not express a functional NHP" can be generated (pg 2, lines 26-28). The specification does not teach any diseases or conditions (particularly inflammation) that are associated with a mutated, deleted, or translocated gene of the instant application (SEQ ID NO: 1). Significant further experimentation would be required by the skilled artisan to identify such a disease or condition, as well as the specific tissues or cells that are involved. Since this asserted utility is also not present in mature form so that it could be readily used in a real world sense, the asserted utility is not substantial.

(ii) Applicant asserts that given the medical relevance of the presently claimed sequences, those of skill in the art would readily appreciate the importance of tracking the expression of the genes encoding the described proteins. Applicant submits that the specification describes how the sequences can be represented using a gene chip format to provide a high throughput analysis of the level of gene expression. Applicant states that DNA chips have utility, as evidence by hundreds of issued U.S. patents. Applicant argues that evidence of the real world substantial utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Applicant asserts that the real world substantial industrial utility of gene sequences appears to be widespread and well established. Applicant also contends that given the widespread utility of "gene chip" methods using public domain gene sequence information, there can be little doubt

that the use of the presently claimed novel and medically relevant sequences would have great utility in such DNA chip applications. Finally, Applicant states that the present sequences are specific markers of the human genome and such specific markers are targets for the discovery of drugs that associated with human disease and those of skill in the art would instantly recognize that the present nucleotide sequences would be ideal, novel candidates for assessing gene expression using DNA chips.

Applicant's arguments have been fully considered but are not found to be persuasive. The specification does not teach the skilled artisan any diseases or conditions associated with a mutated, deleted, translocated, upregulated, or downregulated gene of the instant application (SEQ ID NO: 1). Significant further experimentation would be required of one skill in the art to identify such a disease or condition. Furthermore, whereas a scale or a microarray or a gas chromatograph has patentable utility as a research tool, the objects being evaluated with those research tools do not necessarily have patentable utility. In the instant case, the claimed polynucleotide is not disclosed as having a specific activity, or having any property (such as a differential pattern of expression in diseased tissue) that can be specifically useful. The claimed invention is, in fact, the object of further study, merely inviting further research. Moreover, use of the claimed polypeptide in an array for screening purposes is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. Again, this is a utility which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Applicant's individual polynucleotide is affected by, for example, a test compound in an array for drug screening, the specification does not disclose

any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed polynucleotide has no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding this polynucleotide could be put.

Additionally, as discussed in the previous Office Action (Paper No. 13, 24 September 2002), commercial success requires more than the mere sale of a compound. Commercial success of genomic data is not necessarily evidence of patentable utility. Commercial success is discussed in the MPEP at 716.03 and appears to be applicable to obviousness rejections, but does not appear to be a valid consideration for utility which requires specific, substantial and credible utility. Appellant also has not established a nexus between the *claimed* invention and evidence of commercial success. Appellant's argument is also not persuasive because sale of a compound is not evidence of commercial success and sale of a compound for use as a scientific tool does not appear to be a specific, substantial and credible utility as set forth in the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS".

(iii) Applicant asserts that the present nucleotide sequence has a specific utility in determining genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions. Applicant states that this is evidenced by the fact that SEQ ID NO:1 can be used to map the 5 coding exons on human chromosome 19. Applicant argues that the present polynucleotide provides specificity in localizing to the specific region of human chromosome 19 that contains the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequences. Applicant submits that the presently claimed sequence clearly identified the intron/exon boundaries.

Applicant's arguments have been fully considered but are not found to be persuasive. Although Applicant's asserts that the claimed polynucleotide has a utility in determining genomic structure of the corresponding chromosome, this assertion is credible, but not specific or substantial (see also specification pg 7, line 20). Such assays can be performed with any polynucleotide. The specification does not disclose a specific DNA target or a specific chromosome that contains the claimed polynucleotide. Furthermore, the claimed polynucleotide is not linked to any disease locus. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

(iv) At pg 5 of the Response, it has been indicated that while Applicant is well aware of the new Utility Guidelines set forth by the USPTO, it has been long established that the current rules regarding the examination on patent applications is and always has been the patent laws set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination as set forth by the USPTO. It is stated that Applicant is unaware of any significant recent changes in either 35 U.S.C. § 101 or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. Applicant contends that this is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do no comply with the new Utility Guidelines.

Applicant's arguments have been fully considered but are not found to be persuasive. It is noted that Applicant challenges the legality of the Patent Examination Utility Guidelines. Since an Examiner has no authority to comment on the legality of the Guidelines, this issue must be reserved for ruling by the Board of Patent Appeals and Interferences. The current rejection is

in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial ("real world") utility. Additionally, each Patent Application is examined on its own merits. The invention that was deemed allowable in one patent has no bearing on this application.

4. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth at pg 9-10 of the previous Office Action (Paper No. 16, 28 February 2003) and at pg 6 of the Office Action of 01 April 2002 (Paper No. 11, 01).

Applicant's arguments (Paper No. 16, 28 February 2003) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the above-mentioned reasons.

Applicant argues that the concerns for 35 USC §112, first paragraph have been addressed in the arguments made for 35 USC §101.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, since Applicant has not provided evidence to demonstrate that the claimed nucleic acid molecules have a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
April 28, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER